REMARKS

Status of the Claims

Claims 1-28, 31-39, 42-48, 52-64, 69 and 72-89 remain pending herein.

Support for the amendment to claim 1 can be found, for example, in claim 30.

Claims 4, 7, 11, 14, 19-22, 24, 25, 32, 33, 43, 56-60, 62-64, 72-75, 80-85 and 87-89 have been withdrawn.

Of these withdrawn claims, claims 24, 25 and 87 are members of elected Group II and do not pertain to the species elections (which concerned various linking claims). Reconsideration is requested.

Amendment to the Specification

The specification has been amended above to more accurately state the experimental results set forth in the present specification.

Double Patenting

Various pending claims have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 15-19, 24-26 and 35 of O'Hagan et al. US 6,884,435 (O'Hagan). This rejection and its supporting remarks are respectfully traversed.

For example, claim 1 of the present application is directed to microparticles comprising: (a) a biodegradable polymer; (b) a cationic surfactant; and (c) a first polynucleotide-containing species adsorbed on the surface of the microparticles, *wherein the adsorbed first polynucleotide-containing species constitutes at least 5 percent of the total weight of the microparticles and wherein the microparticles comprise 0.5 to 2 wt% cationic surfactant.*

This claim, particularly the italicized portion thereof, is neither taught nor suggested by the claims of US 6,884,435.

MPEP 804 notes that, when considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the *claim* of a patent, the patent specification can be used as a dictionary to learn the meaning of a term in the

patent claim. However, the disclosure of the patent may not be used as prior art for purposes of an obviousness-type double patenting rejection.

Moreover, even assuming for the sake of argument that the specification could have been used in the double patenting rejection, the general passage from col. 13 cited in the Office Action (i.e., "macromolecules are added to the microparticles to yield microparticles with adsorbed macromolecules having a weight to weight ratio of from about 0.0001:1 to 0.25:1 macromolecules to microparticles, preferably, 0.001:1 to 0.1, more preferably 0.01 to 0.05") does not render the current claims obvious. First, this passage pertains generally to "macromolecules," which are defined at col. 5, lines 65 *et seq.* to "refer to, without limitation, a pharmaceutical, a polynucleotide, a polypeptide, a hormone, an enzyme, a transcription or translation mediator, an intermediate in a metabolic pathway, an immunomodulator, an antigen, an adjuvant, or combinations thereof." There is no statement, however, that these general ranges are applicable *in their entirety to each and every species* embraced by the term "macromolecules," including polynucleotide-containing species. In fact, as seen from Example 7 of O'Hagan et al., actual loads achieved for a polynucleotide-containing species (pCMV) range from 0.84% to 2.36% for target loads of 1% to 4%.

Similarly, there is no teaching that the broad detergent to polymer ratios at col. 13 are applicable in their entirety to each and every microparticle species described in the specification, including those containing cationic detergents, much less cationic detergents in the particular amounts currently claimed.

Furthermore, as seen from Tables 3 and 4 of the present specification, microparticles with moderate amounts of cationic detergent and high polynucleotide loadings like those claimed were unexpectedly found to exhibit enhanced immunogencity, not only relative to naked DNA but also relative to microparticles having higher amounts of cationic detergent. This is surprising, given the higher loading efficiencies observed with higher amounts of cationic detergent.

For at least the above reasons, reconsideration and withdrawal of the outstanding nonstatutory obviousness-type double patenting rejection are requested.

Serial No.: 10/757,708

Provisional Double Patenting

Various claims have been provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over certain claims of copending Application No. 11/113,861. This rejection is a *provisional* rejection. As noted in MPEP 804 I B (emphasis added):

> Occasionally, the examiner becomes aware of two copending applications...that would raise an issue of double patenting ***if one of the applications became a patent.*** ... The merits of such a provisional rejection ***can*** be addressed by both the applicant and the examiner without waiting for the first patent to issue.
>
> The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.
>
> ...
>
> ***If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection*** and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Thus, the double patenting issue has not yet matured for rational argument (i.e., the copending application has not issued as a patent and the claims may be amended in the future). Indeed, at a future time, the provisional double patenting rejection may be the only rejection remaining in the present application, in which case the rejection will be withdrawn in accordance with the provisions of MPEP 804.

Furthermore, Application No. 11/113,861 is a continuation of Application No. 09/581,772, which matured as O'Hagan above. Thus the arguments set forth above in connection with O'Hagan are applicable to the present provisional double patenting rejection as well.

Claim Rejection under 35 USC §101

Claim 50 is rejected under 35 USC §101. This rejection is respectfully traversed. Moreover, this rejection is now moot in view of the cancellation of claim 50 without prejudice of disclaimer.

Rejection under 35 USC §112, 1st paragraph (enablement)--claims 40, 41 and 50

Claims 40, 41 and 50 are rejected under 35 USC §112, 1st paragraph (enablement). This rejection is respectfully traversed. Moreover, this rejection is now moot in view of the cancellation of these claims, without prejudice of disclaimer.

Rejection under 35 USC §112, 1st paragraph (enablement)—claims 39, 42 and 44-48

The rejection of claims 39, 42 and 44-48 under 35 USC §112, 1st paragraph (enablement) is traversed.

Claim 39, from which claims 42 and 44-48 depend, is directed to a method of stimulating an immune response in a host animal, comprising administering to the host animal the microparticle composition of claim 34 in an amount effective to induce an immune response.

According to the examiner, the specification is enabling for a method of stimulating an immune response in a host animal. The examiner, however, further argues that the specification is not enabling for a method of stimulating an immune response *with therapeutic purpose*. In this regard, the examiner considers that language directed to stimulating an immune response is considered to embrace "a composition efficient enough to elicit a protective immune response, when administered to a subject."

In this analysis, the examiner is improperly reading performance standards into the claim that are simply not part of the claim. While it is certainly possible that the claimed method of stimulating an immune response would achieve a therapeutic purpose, the claims do not so require. All that is required is that the specification be enabling for a method of stimulating an immune response in a host animal as claimed, which the examiner admits has been achieved.

Reconsideration and withdrawal of the rejection of claims 39, 42 and 44-48 under 35 USC §112, 1st paragraph (enablement) are requested.

Rejection under 35 USC §112, 1st paragraph (enablement)—claim 38

Claim 38 is rejected under 35 USC §112, 1st paragraph (enablement). This rejection is respectfully traversed.

Moreover, this rejection is now believed to be moot in view of the above amendment of claim 38. As observed by the examiner, the specification is enabling for a method of delivering a polynucleotide-containing species to a host animal.

Reconsideration and withdrawal of the rejection of claim 38 under 35 USC §112, 1st paragraph (enablement) are requested.

Claim rejection under 35 USC §102(e)—O'Hagan

Various claims are rejected under 35 USC §102(e) as being anticipated by O'Hagan. This rejection is traversed.

As noted above, O'Hagan doesn't teach or suggest microparticles in which an adsorbed polynucleotide-containing species constitutes at least 5 percent of the total weight of the microparticles and in which the microparticles comprise 0.5 to 2 wt% cationic surfactant. Moreover, microparticles with moderate amounts of cationic detergent and high polynucleotide loadings as claimed were unexpectedly found to exhibit enhanced immunogencity, not only relative to naked DNA, but also relative to microparticles having higher amounts of cationic detergent. This is surprising, given the higher loading efficiencies observed with higher amounts of cationic detergent.

For at least these reasons, reconsideration and withdrawal of claim rejection under 35 USC §102(e) are requested.

Claim rejection under 35 USC §103(a)—Singh

Various claims are rejected under 35 USC §103(a) as being unpatentable over Singh et al., *Proc. Natl. Acad. Sci. USA*, 2000, 97:811-816 (Singh). This rejection is traversed.

As with O'Hagan, Singh doesn't teach or suggest microparticles in which an adsorbed polynucleotide-containing species constitutes at least 5 percent of the total weight of the microparticles and in which the microparticles comprise 0.5 to 2 wt% cationic surfactant.

With respect to the claimed ranges, the examiner cites MPEP 2144.05 and urges that, absent unexpected results, it would have been obvious to one or ordinary skill in the art to vary these parameters, with the purpose of optimizing. Applicant disagrees.

First, as noted above, microparticles with moderate amounts of cationic detergent and high polynucleotide loadings as claimed were unexpectedly found to exhibit enhanced immunogencity, not only relative to naked DNA, but also relative to microparticles having higher amounts of cationic detergent.

Moreover, as noted in MPEP 2144.05, a particular parameter must first be recognized as a result-effective variable before it can be argued that it is obvious to optimize the parameter, and the examiner has presented no evidence that the claimed parameters are so recognized.

For at least the above reasons, reconsideration and withdrawal of claim rejection under 35 USC §103(a) over Singh are requested.

Claim rejection under 35 USC §103(a)—Singh and Thalhamer

Various claims are rejected under 35 USC §103(a) as being unpatentable over Singh and further in view of Thalhamer et al., *Endocrine Regulations*, 2001, 35:143-166 (Thalhamer) as evidenced by Diwan et al., *Journal of Controlled Release*, 2002, 85:247-262 (Diwan). This rejection is traversed.

Various deficiencies in Singh as a reference are noted above. Thalhamer and Diwan, which are cited for their teachings regarding CpG adjuvants, do not make up for those deficiencies in Singh. Moreover, while Thalhamer and Diwan may teach CpG adjuvants, they do not teach adsorbing them to microparticles as claimed in certain claims (see, e.g., claim 8).

For at least the above reasons, reconsideration and withdrawal of the claim rejection under 35 USC §103(a) based on Singh, Thalhamer and Diwan are requested.

CONCLUSION

Applicant submits that this application is in condition for allowance, early notification of which is earnestly solicited. The Examiner is encouraged to contact the undersigned at (703) 433-0510 to discuss any outstanding issues in this case.

FEES

The Office is authorized to charge any fees required in connection with this application, to deposit account number 50-1047.

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I hereby certify that this document and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on Oct. 2, 2006.

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